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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
• 09/898,586	07/03/2001	Valerie L. Gerlach	15966-638CIP (Cura-138CIP)	2872

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EXAMINER

LI, RUIXIANG

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 06/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/898,586	GERLACH ET AL.	
	Examiner	Art Unit	
	Ruixiang Li	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19 and 80-83 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19 and 80-83 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

I. Status of Application, Amendments, and/or Claims

The amendment filed in Paper No. 15 on April 14, 2003 has been entered in full. Claim 19 has been amended. Claims 80-83 have been added. Claims 19 and 80-83 are pending and under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

II. Claim Rejections Under 35 U. S. C. § 112, 1st Paragraph—New Matter

Claims 19 and 80-83 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification merely discloses SEQ ID NO: 3, which comprises the 5' untranslated region (nucleotides 1-54 of SEQ ID NO: 23). However, there is no support in the specification for a nucleic acid molecule comprising a nucleic acid sequence encoding a polypeptide comprising the amino acid sequence of SEQ ID NO: 24 and further comprising the nucleotides of the 5' untranslated region of SEQ ID NO: 23 or a variant. This is a new matter rejection.

III. Claim Rejections Under 35 U. S. C. § 112, 2nd Paragraph

(i) The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

(ii). Claims 19 and 80-83 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 19 is indefinite because it recites "or the complement of said nucleic acid sequence" (line 6). It is unclear which nucleic acid sequence it refers to, rendering the claim indefinite. Claims 80-83 depend from claim 19. It is suggested that the limitation "or the complement of said nucleic acid sequence" be placed right after "A method for determining the presence or amount of a nucleic acid molecule" (beginning of line 2).

IV. Claim Rejection under 35 USC § 102 (e)

The rejection of claim 19 under 35 U.S.C. § 102 (e) as being anticipated by Au-Young et al. (WO200107612A2, 102 (e) date: July 21, 1999), as set forth at page 3 of the previous Office Action (Paper No. 14, January 15, 2003), remains.

Newly added claims 80-83 are also rejected under 35 U.S.C. § 102 (e) as being anticipated by Au-Young et al. (WO200107612A2, 102 (e) date: July 21, 1999). The basis for the rejection is set forth at page 3 of the previous Office Action (Paper No. 14, January 15, 2003).

Au-Young et al. teach a method for determining the presence or amount of such a nucleic acid in a sample (claim 13). Au-Young et al. further teach an isolated polynucleotide comprising a nucleic acid sequence (SEQ ID NO: 41 of claim 11) encoding the amino acid sequence of SEQ ID NO:24.

It is noted that Applicants have amended claim 19 with a limitation, "further comprising nucleotides 45-54 of SEQ ID NO: 23 or a variant thereof, wherein said variants comprises a nucleic acid wherein one nucleotide is changed from the nucleotides 45-54 of SEQ ID NO: 23". However, the present invention is drawn to a method for determining the presence or amount of a nucleic acid in a sample, a probe that binds to the nucleic acid sequence taught by Au-Young et al. would also bind to the nucleic acid recited in the preamble. In addition, the steps set forth in the method do not distinguish the nucleic acid sequence taught by Au-Young et al. from the nucleic acid sequence recited in the preamble. Thus, the reference of Au-Young et al. meets the limitations of claims 19 and 80-83.

V. Claim Objection

Claims 80-83 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claims 80-83 all depend upon claim 19. The difference among claims 19 and 80-83 is the limitation, "further comprising...". Claim 19 recites "further comprising

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nucleotides 45-54 of SEQ ID NO: 23 or a variant thereof, wherein said variants comprises a nucleic acid wherein one nucleotide is changed from the nucleotides 45-54 of SEQ ID NO: 23"; claim 80 recites "further comprising nucleotides 35-54 of SEQ ID NO: 23 or a variant thereof, wherein said variants comprises a nucleic acid wherein one nucleotide is changed from the nucleotides 35-54 of SEQ ID NO: 23"; claim 81 recites "further comprising nucleotides 25-54 of SEQ ID NO: 23 or a variant thereof, wherein said variants comprises a nucleic acid wherein one nucleotide is changed from the nucleotides 25-54 of SEQ ID NO: 23"; and so on. It is noted that the nucleotides of 5' untranslated region of SEQ ID NO: 23 comprised in the limitation overlap with the limitation of claim 19. Thus, claims 80-83 fail to further limit claim 19.

VI. Conclusion

No claims are allowed.

VII. Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (703) 306-0282. The examiner can normally be reached on Monday-Friday, 8:30 am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 305-3014 or (703) 308-4242.

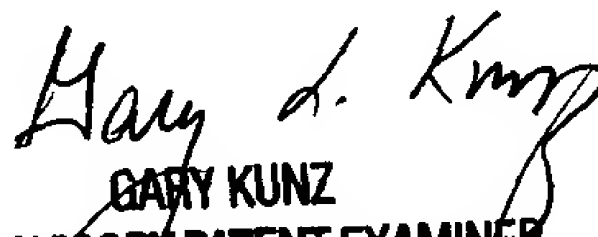
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Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Ruixiang Li
Examiner
June 11, 2003


GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600